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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) Shults et al. Examiner: Unassigned
Serial No.: 09/447,227 Group Art Unit: 1744
Confirmation No.: Docket: 1146-4 DIV
Filed: November 22, 1999 Dated: July 19, 2001
For: DEVICE AND METHOD
FOR DETERMINING
ANALYTE LEVELS

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Date: July 19, 2001
Signature: K.J. Goodhand *K.J. Goodhand*

INFORMATION DISCLOSURE STATEMENT

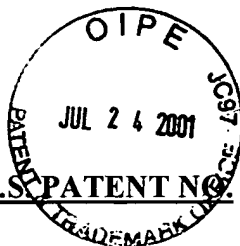
Sir:

In fulfillment of the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicant submits herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and 1.98.

As this Information Disclosure Statement is being filed with the application and before the issuance of the first Office Action, no fee is deemed necessary.

I. U.S. PATENTS

| <u>U.S. PATENT NO.</u> | <u>TITLE</u> | <u>ISSUE DATE</u> |
|-------------------------------|------------------------------------|--------------------------|
| * 4,353,888 to Selfton | Encapsulation of Live Animal Cells | October 12, 1982 |
| * 4,431,004 to Bessman et al. | Implantable Glucose Sensor | February 14, 1984 |



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| | | |
|--------------------------------|--|-------------------|
| 4,436,094 to Cerami | Monitor for Continuous in Vivo Measurement of Glucose Concentration | March 7, 1984 |
| 4,484,987 to Gough | Method and Membrane Applicable to Implantable Sensor | November 29, 1984 |
| * 4,686,044 to Behnke et al. | Polycarbonate-Polyether-Copolymer Membrane | August 11, 1987 |
| * 4,703,756 to Gough et al. | Complete Glucose Monitoring System with an Implantable, Telemetered Sensor Module | November 3, 1987 |
| * 4,757,022 to Shults et al. | Biological Fluid Measuring Device | July 12, 1988 |
| * 4,787,398 to Garcia et al. | Glucose Medical Monitoring System | November 29, 1988 |
| * 4,803,243 to Fujimoto et al. | Block-Graft Copolymer | February 7, 1989 |
| * 4,823,808 to Clegg et al. | Method for Control of Obesity, Overweight and Eating Disorders | April 25, 1989 |
| * 4,902,294 to Gosserez | Implantable Mammary Prosthesis Adapted to Combat the Formation of Retractable Shell | February 20, 1990 |
| * 4,994,167 to Shults et al. | Biological Fluid Measuring Device | February 19, 1991 |
| * 5,190,041 to Palti | System for Monitoring and Controlling Blood Glucose | March 2, 1993 |
| 5,314,471 to Brauker et al. | Tissue Implant Systems and Methods for Sustaining Viable High Cell Densities Within a Host | May 24, 1994 |
| * 5,321,414 to Alden et al. | Dual Polarization Dipole Array Antenna | June 14, 1994 |
| 5,344,454 to Clarke et al. | Closed Porous Chambers for Implanting Tissue in a Host | September 6, 1994 |

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| <u>U.S. PATENT NO.</u> | <u>TITLE</u> | <u>ISSUE DATE</u> |
|-----------------------------------|--|--------------------|
| * 5,380,536 to Hubbell et al. | Biocompatible Microcapsules | January 10, 1995 |
| 5,417,395 to Fowler et al. | Modular Interconnecting Component Support Plate | May 23, 1995 |
| 5,421,923 to Clarke et al. | Ultrasonic Welding Horn with Sonics Dampening Insert | June 6, 1995 |
| * 5,431,160 to Wilkins | Miniature Implantable Refillable Glucose Sensor and Material Therefor | July 11, 1995 |
| * 5,453,278 to Cham et al. | Laminated Barriers for Tissue Implants | September 26, 1995 |
| 5,462,064 to D'Angelo et al. | Integrated System for Biological Fluid Constituent Analysis | October 31, 1995 |
| * 5,469,846 to Khan | Implantable Non-Enzymatic Electrochemical Glucose Sensor | November 28, 1995 |
| * 5,476,094 to Allen et al. | Acrylic Copolymer Membranes for Biosensors | December 19, 1995 |
| * 5,497,772 to Schulman et al. | Glucose Monitoring System | March 12, 1996 |
| 5,545,223 to Neuenfeldt et al. | Ported Tissue Implant Systems and Methods of Using Same | August 13, 1996 |
| 5,549,675 to Neuenfeldt et al. | Method for Implanting Tissue in a Host | August 23, 1996 |
| 5,569,462 to Martinson et al. | Methods for Enhancing Vascularization of Implant Devices | October 29, 1996 |
| 5,578,463 to Berka et al. | Heterologous Polypeptides Expressed in Filamentous Fungi, Processes for Making Same, and Vectors for Making Same | November 26, 1996 |
| 5,593,440 to Brauker et al. | Tissue Implant Systems and Methods for Sustaining Viable High Cell Densities Within a Host | January 14, 1997 |

| <u>U.S. PATENT NO.</u> | <u>TITLE</u> | <u>ISSUE DATE</u> |
|-----------------------------------|---|--------------------|
| 5,653,756 to Clarke et al. | Closed Porous Chambers for Implanting Tissue in a Host | August 5, 1997 |
| * 5,660,163 to Schulman et al. | Glucose Sensor Assembly | August 26, 1997 |
| 5,713,888 to Neuenfeldt et al. | Tissue Implant Systems | February 3, 1998 |
| 5,733,336 to Neuenfeldt et al. | Ported Tissue Implant Systems and Methods of Using Same | March 31, 1998 |
| * 5,741,330 to Brauker et al. | Close Vascularization Implant Material | April 21, 1998 |
| 5,782,912 to Brauker et al. | Close Vascularization Implant Material | July 21, 1998 |
| 5,800,529 to Brauker et al. | Close Vascularization Implant Material | September 1, 1998 |
| 5,807,406 to Brauker et al. | Porous Microfabricated Polymer Membrane Structures | September 15, 1998 |
| 5,882,354 to Brauker et al. | Close Vascularization Implant Material | March 16, 1999 |
| 5,964,261 to Neuenfeldt et al. | Implantation Assembly | October 12, 1999 |
| 6,122,536 to Sun et al. | Implantable Sensor and System for Measurement and Control of Blood Constituent Levels | September 19, 2000 |
| 6,208,894 to Schulman et al. | System of Implantable Devices for Monitoring and/or Affecting Body Parameters | March 27, 2001 |
| 6,212,416 to Ward et al. | Device for Monitoring Changes in Analyte Concentration | April 3, 2001 |
| 6,256,522 B1 to Schultz | Sensors for Continuous Monitoring of Biochemicals and Related Method | July 3, 2001 |

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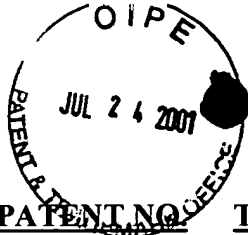
August 5, 1997

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U.S. PATENT NO. **TITLE**

6,259,937 to
Schulman et al.

Implantable Substrate Sensor

ISSUE DATE

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II. FOREIGN PATENT DOCUMENTS

| <u>PATENT NO.</u> | <u>COUNTRY</u> | <u>ISSUE DATE</u> |
|--------------------------|-----------------------|--------------------------|
| WO 90/00738 | PCT | January 25, 1990 |
| * WO 92/07525 | PCT | May 14, 1992 |
| * WO 92/13271 | PCT | August 6, 1992 |
| * WO 94/22367 | PCT | October 13, 1994 |
| * WO 96/01611 | PCT | January 25, 1996 |
| * WO 96/32076 | PCT | October 17, 1996 |
| * WO 96/36296 | PCT | November 21, 1996 |

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III. NON-PATENT DOCUMENTS

- * 1. Updike et al., "Laboratory Evaluation of New Reusable Blood Glucose Sensor," *Diabetes Care*, 11:801-807 (1988).
- * 2. Moatti-Sirat et al., "Towards Continuous Glucose Monitoring: In Vivo Evaluation of a Miniaturized Glucose Sensor Implanted for Several Days in Rate Subcutaneous Tissue," *Diabetologia* 35:224-30 (1992).
- * 3. Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," *Diabetes* 39:1519-26 (1990).
- * 4. Woodward, "How Fibroblasts and Giant Cells Encapsulate Implants: Considerations in Design of Glucose Sensor," *Diabetes Care* 5:278-281 (1982).
- * 5. Bindra et al., "Design and In Vitro Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring," *Anal. Chem.* 63:1692-96 (1991).

- *6. Shults et al., A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Impaired Glucose Sensors, *IEEE Trans. Biomed. Eng.* 41:937-942 (1994).
- *7. Phillips and Smith, "Biomedical Applications of Polyurethanes: Implications of Failure Mechanisms," *J. Biomat. Appl.* 3:202-227 (1988).
- *8. Stokes, "Polyether Polyurethanes: Biostable or Not?," *J. Biomat. Appl.* 3:228-259 (1988).
- *9. Updike et al. Enzymatic Glucose Sensors: Improved Long-Term Performance In Vitro and In Vivo, *Am.Soc. Artificial Internal Organs* 40:157-163 (1994).
- *10. Updike et al., Implanting the Glucose Enzyme Electrode: Problems, Progress, and Alternative Solutions," *Diabetes Care* 5:207-21 (1982).
- *11. Rhodes et al., "Prediction of Pocket-Portable and Implantable Glucose Enzyme Electrode Performance from Combined Species Permeability and Digital Simulation Analysis," *Anal. Chem.* 66:1520-1529 (1994).
- *12. Tse and Gough, Time-Dependent Inactivation of Immobilized Glucose Oxidase and Catalase, *Biotechnol. Bioeng.* 29:705-713 (1987).
- *13. Gilligan et al., "Evaluation of a Subcutaneous Glucose Sensor Out to 3 Months in a Dog Model," *Diabetes Care* 17:882-887 (1994).
- *14. McKean and Gough, "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," *IEEE Trans. Biomed. Eng.* 35:526-532 (1988).
- *15. Shichiri et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor-A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," *Diabetes Care* 9:298-301 (1986).
- *16. Lyman, "Polyurethanes. I. The Solution Polymerization of Diisocyanates with Ethylene Glycol," *J. Polymer Sci.* 45:49 (1960).
- *17. DuPont¹ Dimension AR® (Catalog).
- *18. Direct 30/30® meter (Markwell Medical) (Catalog).
- *19. Fischer et al., "Oxygen Tension at the Subcutaneous Implantation Site of Glucose Sensors," *Biomed. Biochem.* 11/12, 965-972 (1989).
- *20. Brauker et al., "Neovascularization of Synthetic Membranes Directed by Membrane Microarchitecture," *Journal of Biomedical Materials Research* 29:1517 (1995).

*21. Abstract presented by James Brauker, Ph.D., "Neovascularization of Cell Transplantation Devices: Membrane Architecture-Driven and Implanted Tissue-Driven Vascularization," Baxter Healthcare Corp.


22. Brauker et al., "Local Inflammatory Response Around Diffusion Chambers Containing Xenografts", Transplantation, Vol. 61, 1671-1677, No. 12, June 27, 1996.

Copies of each of the references denoted by an asterisk (*) have been previously cited in related application, U.S. Serial No. 08/811,473, now Patent No. 6,001,067, issued December 14, 1999. Accordingly, the Examiner is invited to refer to such prior application for copies of each of the references. Copies of references not previously cited are submitted herewith.

All of the references listed above are also listed on Applicant's Substitute Form PTO-1449 which is attached to this Information Disclosure Statement for the convenience of the Examiner.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,


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